Remarks/Arguments

Claims 1, 6-9, 11, 15-17 and 21-34 remain in this application.

With respect to the Office Action's assertion that ethyl cellulose is a cellulose ester, Applicant respectfully disagrees. A definition was provided with in the Office Action that is incorrect. The correct definition is enclosed herewith, whereby ethyl cellulose is defined as an "ethyl ether of cellulose" (emphasis added). In addition, Applicant encloses a copy of a chemical structure, which is the chemical structure of ethyl cellulose. Please note that there are no ester functional groups. Therefore, it cannot be a cellulose ester.

Claim Rejections-35 U.S.C. § 103

Claims 17, 21, 23, 30 and 33 are continued to be rejected under 35 U.S.C. §103(a) as being unpatentable over Japanese Patent No. 03197421 to Hirashima (hereinafter "Hirashima"). The Office Action asserts that the amount of both PEG and polymer taught in Hirashima and the instant invention only differs by 10% and for this reason it is necessary for the Applicant to show the criticality of these small differences.

Independent Claims 17, 23 and 33 are directed to an extended release pharmaceutical active formulation comprising an encasement coat being non-permeable and soluble in a pH of above about 5.0 and comprising about 5 to less than 50% by weight of polymer and 0.5%-30% by weight PEG or 0.5%-30% by weight plasticizer comprising polyethylene glycol in the coat. The polymer used in Hirashima is ethyl cellulose. Ethyl cellulose is non-enteric, which means that it will dissolve at an acidic pH; non-enteric compounds will dissolve in the stomach. Therefore, a coat of ethyl cellulose will dissolve to form pores at any pH in the gastric range and thereby release its contents without lag time. In contrast, the extended release formulation of the claimed invention will remain intact until experiencing a pH of above about 5, and will only then dissolve, therefore providing an extended release. For these reasons, one skilled in the art would not consider using ethyl cellulose as the polymer in the claimed invention since the claimed criterion of the encasement coat, wherein the coat is soluble in a pH above about 5, would not be

satisfied. Therefore, it is not necessary for the Applicant to show the criticality of differences in percentages of the coating compositions of Hirashima and the claimed invention since ethyl cellulose would not be used as a polymer to provide the function specified in the claimed invention; soluble in a pH above about 5. Therefore, Hirashima does not teach or suggest a coat having the properties of the coat of the claimed invention.

For these reasons, it is respectfully submitted that independent Claims 17, 23 and 33 are patentable over Hirashima and consequently, Claims 21 and 30, which are dependent, or ultimately dependent, from Claim 17, are also patentable over Hirashima.

Claim Rejections- 35 U.S.C. §112, first paragraph

Claims 1, 6-9, 15-17, and 21-34 are rejected under 35 USC 112, first paragraph. The Office Action asserts that there is no reasonable enablement for the polymeric film being cellulose esters. The Office Action notes, for example, that the invention requires that the polymeric film be non-permeable and that the instant invention can use cellulose esters to formulate the non-permeable film; however, U.S. Patents Nos. 6,099,859 to Cheng et al. (hereinafter "Cheng") and 6,106,864 to Dolan et al. (hereinafter "Dolan") disclose that cellulose esters are semi-permeable rather than non-permeable.

The Office Action asserts that "Applicant argues that Dolan discloses that cellulose esters are semi-permeable rather than non-permeable. Dolan describes cellulose acetate as being both impermeable and semi-permeable". It is submitted that Applicant did not argue that Dolan "discloses that cellulose esters are semi-permeable rather than non-permeable." This was an actual statement made in the previous Office Action dated March 26, 2007. In fact, Applicant asserted that Dolan teaches that cellulose acetate is described as being both impermeable and semi-permeable (see column 3, lines 11-22 and 32-27). Since cellulose acetate is, however, non-enteric, one skilled in the art would not consider using in the encasement coat of the claimed invention, cellulose acetate as the polymer, or more specifically the cellulose ester, of the claimed invention since cellulose acetate would dissolve and form a semi-permeable membrane in a pH below 5.0. Therefore, one skilled in the art would know to choose cellulose esters, such

as enteric cellulose esters, that would yield the specifically claimed properties of the encasement coat. Therefore, cellulose esters are enabled in the context of the claimed invention.

Claim Rejections- 35 U.S.C. §103(a)

Claims 1, 6-9, 11, 15-17, and 21-34 are rejected under 35 U.S.C. §103(a) as being unpatentable over U.S. Patent No. 6,106,864 to Dolan et al. (hereinafter "Dolan") and U.S. Patent No. 5,800,422 to Dong et al. (hereinafter "Dong") and U.S. Patent No. 6,099,859 to Cheng (hereinafter "Cheng").

The Office Action asserts that Dolan teaches oral dosage forms of actives and teaches that a matrix comprising the active can be coated with an impermeable coating (see column 2, lines 53-57; see column 3, lines 1-7). It is submitted, however, that Dolan actually teaches that the impermeable coating is provided with an aperture (see column 3, lines 1-7).

The Office Action also asserts that Dolan teaches that ingredients can be formulated into a tablet which can be coated with shellac, phthalate derivatives as well as with semi-permeable coatings such as cellulose esters (ethyl cellulose, cellulose acetate) and acrylic polymers (see column 3, lines 7-38). (Please note that ethyl cellulose is not a cellulose ester). Dolan's coat is **either** impermeable, as noted in (c) at column 2, lines 42-44 and column 3, lines 11-21, **or** the coat can have low aqueous solubility (e.g. water soluble at pH >5), as noted in (d) at column 2, lines 46-47, and column 3, lines 22-30. As discussed above with respect to 35 USC 112, first paragraph, Dolan teaches the use of non-enteric cellulose esters, such as cellulose acetate, in conjunction with an impermeable coat, as noted in (c) at column 3, lines 11-21, and with a semi-permeable coat, as noted in (e) at column 3, lines 32-37. Dolan does not teach or suggest an encasement coat, as a whole, being both non-permeable and soluble in a pH of above about 5.0.

The Office Action asserts that Dolan teaches that the coating can be made using ethyl cellulose. The Office Action acknowledges that none of the claims can comprise ethyl cellulose and further asserts that ethyl cellulose is a cellulose ester. As discussed above, ethyl cellulose is not a cellulose ester.

The Office Action further asserts that since ethyl cellulose can be used to form an impermeable coat as well as a semi-permeable coat, it is necessary for Applicant to show what kind of coating is produced with the specific percentages claimed. Applicant submits that ethyl cellulose, as discussed above with respect to Hirashima, would not be chosen as a polymer in the claimed invention since ethyl cellulose is soluble and would form pores in a pH below 5.0; it is soluble at acidic pH.

The Office Action also asserts that it is imperative that Applicant shows that his invention produces a non-permeable membrane using a cellulose ester since Dolan only teaches the production of impermeable and semi-permeable membranes using ethyl cellulose. The Office Action again asserts that ethyl cellulose is a cellulose ester. As discussed above, ethyl cellulose is not a cellulose ester. Moreover, Dolan does not teach or suggest an encasement coat, as a whole, being both non-permeable and soluble in a pH of above about 5.0. Applicant again submits that ethyl cellulose, as discussed above with respect to Hirashima, would not be chosen as a polymer in the claimed invention since ethyl cellulose is soluble and would form pores in a pH below 5.0; it is soluble at acidic pH.

The Office Action further asserts that Dolan with Dong and Cheng yield a coating comprising ethyl cellulose and PEG in the percentages claimed and also asserts that it would be inherent for the coating to have the same properties as that of the claimed invention. As discussed above with respect to Hirashima, ethyl cellulose is non-enteric, which means that it will dissolve and form pores at an acidic pH; non-enteric compounds will dissolve in the stomach. Therefore, ethyl cellulose will be soluble and form pores at a pH below 5. . In contrast, the extended release formulation of the claimed invention will remain intact in the stomach since the encasement coat will not dissolve below a pH of 5, therefore providing an extended release. For these reasons, one skilled in the art would not consider using ethyl cellulose as the polymer in the claimed invention since the claimed criterion of the encasement coat, wherein the coat is soluble in a pH above about 5, would not be satisfied. As a result, it would not be inherent for the coat of Dolan with Dong and Cheng to have the same properties as the coat of the claimed invention, as asserted by the Office Action.

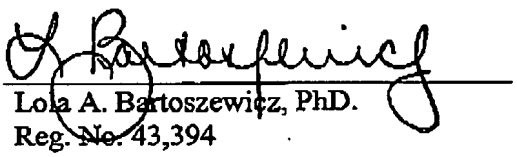
For these reasons, it is respectfully submitted that Claims 1, 6-9, 11, 15-17, and 21-34 are patentable over Dolan, Dong and Cheng. Dong and Cheng do not overcome the above-noted deficiencies of Dolan.

Conclusion

In view of the foregoing, reconsideration of the application, withdrawal of the outstanding rejections, allowance of all of the pending claims 1, 6-9, 11, 15-17, 21-34, and the issuance of a Notice of Allowability are respectfully solicited.

In the event that this paper is not considered to be timely filed, the Applicant respectfully petitions for an appropriate extension of time. Any fees for such an extension, together with any additional fees that may be due with respect to this paper, may be charged to Sim & McBurney's Account No. **192253**, referencing docket number 9577-25 LAB.

Respectfully submitted,
SIM & McBURNEY

By 
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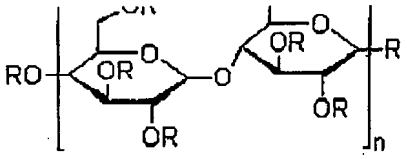

R = H or Et

ETHYL CELLULOSE

Prepared at the 26th JECFA (1982), published in FNP 25 (1982) and FNP 52 (1992)

Library home

JECFA specifications

- Agar
- Alginic acid
- Ammonium alginate
- Calcium alginate
- Carrageenan
- Cellulose powder
- CMC
- CMC, enzyme hydrolysed
- Cyclodextrin
- Ethyl cellulose
- Ethyl hydroxyethyl cellulose
- Gelatin
- Gellan gum
- Guar gum
- Gum arabic
- Gum ghatti
- Gum tragacanth
- HPMC
- Hydroxypropyl cellulose
- Karaya gum
- Konjac flour
- Locust bean gum
- Methyl cellulose
- Methyl ethyl cellulose
- Microcrystalline cellulose
- Pectin
- Potassium alginate
- Processed eucheuma seaweed
- Propylene glycol alginate
- Sodium alginate
- Tara gum
- Xanthan gum

SYNONYMS

INS No. 462

DEFINITION

Ethyl ether of cellulose, prepared from wood pulp or cotton by treatment with alkali and ethylation of the alkali cellulose with ethyl chloride. The article of commerce can be specified further by viscosity.

Chemical names

Cellulose ethyl ether, ethyl ether of cellulose

C.A.S. number

9004-57-3

Assay

Not less than 44% and not more than 50% of ethoxyl groups (-OC_2H_5) on the dried basis (equivalent to not more than 2.6 ethoxyl groups per anhydroglucose unit).

DESCRIPTION

Free-flowing, white to light tan powder

FUNCTIONAL USES

Tableting aid, binder, filler, diluent of colour and other food additives

CHARACTERISTICS

IDENTIFICATION

Solubility

Practically insoluble in water, in glycerol, and in propane-1,2-diol, but soluble in varying proportions in certain organic solvents, depending upon the ethoxyl content. Ethyl cellulose containing less than 46-48% of ethoxyl groups is freely soluble in tetrahydrofuran, in methyl acetate, in chloroform, and in aromatic hydrocarbon ethanol mixtures. Ethylcellulose containing 46-48% or more of ethoxyl groups is freely soluble in ethanol, in methanol, in toluene, in chloroform, and in ethyl acetate.

Film forming test

Dissolve 5 g of the sample in 95 g of an 80:20 (w/w) mixture of toluene-ethanol. A clear, stable, slightly yellow solution is formed. Pour a few ml of the solution onto a glass plate, and allow the solvent to evaporate. A thick, tough continuous, clear film remains. The film is flammable.

pH

Neutral to litmus (1 in 20 suspension)

PURITY

Loss on drying

Not more than 3% (105°, 2 h)

Sulfated ash

Not more than 0.4%

Test 1 g of the sample (Method I)

Arsenic

Not more than 3 mg/kg (Method II)

Lead

Not more than 10 mg/kg

Heavy metals

Not more than 40 mg/kg

Test 0.5 g of the sample as directed in the Limit Test (Method II)

METHOD OF ASSAY

Determine the ethoxyl content as directed under *Ethoxyl and Methoxyl Group Determination*.